UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JAMES N. BATES and STEPHEN J. LEWIS

Appeal No. 2006-2587
Application No. 09/879,710

HEARD: October 17, 2006

Before ADAMS, GREEN and LEBOVITZ, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 2-8 and 10, which are all the claims pending in the application.

Claim 10 is illustrative of the subject matter on appeal and is reproduced below[1]:

10. A method of counter acting the overproduction of nitric oxide which often occurs in hypotension and shock, consisting essentially of: administering to a patient a therapeutically effective amount of an S-alkylthiol as an antagonist of S-nitrosothiols.

[1] All of the remaining claims before us on appeal ultimately depend from claim 10.

The references relied upon by the examiner are:

Joullié et al. (Joullié)	3,892,852	Jul. 1, 1975
Meisner	4,772,591	Sep. 20, 1988

Chemical Abstracts (Chem. Abst.), "L-Cysteine, S-methyl- (9CI)," Registry No. 1187-84-4

GROUNDS OF REJECTION

Claims 2, 3, 8 and 10 stand rejected under 35 U.S.C. § 102(b) as anticipated by Meisner.

Claims 2-8 and 10 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Meisner, Joullié and Chem. Abst.

We reverse.

DISCUSSION

Anticipation:

"Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim." Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997). "Every element of the claimed invention must be literally present, arranged as in the claim." Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

The examiner finds (Answer, page 4), "Meisner teaches that a composition containing among other ingredients, an anti-inflammatory substance, specifically, S-methylcysteine is administered to a patient." According to the examiner (id.), "[e]ven though the composition is administered to the patient for a

different reason in the reference, it would have been inherent to the process of Meisner that nitric oxide synthesis is inhibited since the steps of the processes (Meisner and the instant application) are the same."

In response, appellants point out that the claims on appeal use the transitional phrase "consisting essentially of." Brief, page 4. In this regard, we note, "'[c]onsisting essentially of' is a transition phrase commonly used to signal a partially open claim in a patent. . . . By using the term 'consisting essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention." PPG Indus. Inc. v. Guardian Indus. Corp, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998).

According to appellants (Brief, page 4), Meisner's composition requires four ingredients, one of which is "a precursor or stimulant of epinephrine or nor-epinephrine production selected from tyrosine, and phenylalanine. . . ." In this regard appellants point out (Brief, page 5),

> At the time of filing of the present application, current treatments options for hypotension or septic shock have been limited to vasoconstricting agents that have many deleterious side effects that limit their therapeutic usage. (Spec. p. 2, lines 11-16). Therefore, a primary goal of the present invention was the development of effective pharmacological treatments to counteract hypotension and shock without the deleterious side effects associated with the use of vasoconstricting agents. (Spec. p. 2, lines 11-19).

According to appellants (Brief, page 6, emphasis removed), "[e]phinephrine and norepinephrine are well known . . . potent vasoconstricting agents." Accordingly, appellants assert that adding a precursor or stimulant of epinephrine or

norepinephrine production selected from tyrosine, and phenylalanine to their claimed composition "would 'materially affect the basic and novel characteristic(s)[ ] of the claimed invention.'" Brief, page 6.

For his part, the examiner asserts that appellants' argument is "without merit" because, as we understand his argument, S-methylcysteine may also be a vasoconstricting agent. Answer, page 7. The examiner, however, fails to favor this record with any evidence to support this assertion. Accordingly, we do not find this argument persuasive.

As we understand it, the examiner also asserts, (id.), that appellants' claims do not require the patient to suffer from any particular disease. Accordingly, the examiner finds appellants' argument with regard to the "avoiding the side effects of vasoconstrictors" to be without merit since the claimed composition can be administered to "anyone . . . no matter what there need is." It appears that the examiner's argument relates to the phrase "which often occurs in hypotension and shock", as it appears in claim 10 on appeal. For clarity, we note that while claim 10 states that the overproduction of nitric oxide often occurs in hypotension and shock, claim 10 and its dependent claims are not specifically limited to the treatment of hypotension and shock. Hypotension and shock are just two of any number of conditions[2] encompassed by appellants' claimed invention that may require the overproduction of nitric oxide to be counter acted. We note, however, that the examiner appears to intimate that the claims do not

[2] See e.g., appellants' specification, page 2, last paragraph, wherein appellants disclose "[c]onditions other than hypotension that might benefit from inhibition of the actions of nitric oxide and nitrosothiols include, but are not limited to, chronic and acute pain, hypoxemia secondary in part to the loss of hypoxic pulmonary vasoconstriction, uterine atony, and decreased tone and peristalsis of gastrointestinal smooth muscle."

require the achievement of a particular result. This is incorrect. By administering the composition to a patient, the claims require that the composition counter act the overproduction of nitric oxide.

Further, we find the examiner's comments regarding the side effects of vasoconstrictors to be off base. The question is whether the basic and novel characteristics of appellants' claimed composition will be changed by adding a known vasoconstrictor to the claimed composition. According to appellants' specification (page 2), "[c]urrent treatment options for hypotension or shock . . . are limited to vasoconstricting agents that have many deleterious side effects that limit their effective therapeutic usage." Focusing on hypotension and shock appellants disclose (id.), "[i]t therefore can be seen that there is a continuing need for the development of effective pharmacological treatments to counteract hypotension and shock. . . . This invention has as its primary objective the fulfillment of this need." Based on this portion of their specification, appellants assert (Brief, page 5, emphasis) that "a primary goal of the present invention was the development of effective pharmacological treatments to counteract hypotension and shock without the deleterious side effects associated with the use of vasoconstricting agents."

In our opinion, a person of ordinary skill in the art would recognize that adding a vasoconstricting agent such as a precursor or stimulant of epinephrine or norepinephrine production selected from tyrosine, and phenylalanine, as taught by Meisner, to appellants' claimed invention would affect the basic and

novel characteristics of appellants' claimed invention. Accordingly, we are not persuaded by the examiner's arguments to the contrary.

On reflection, we find that the weight of the evidence falls in favor of appellants in that "a precursor or stimulant of epinephrine or norepinephrine production selected from tyrosine, and phenylalanine" will materially affect the basic and novel characteristics of appellants' claimed invention. As such, since Meisner's composition requires that such a precursor or stimulant be present in the composition, Meisner cannot anticipate appellants' claimed invention.

Accordingly, we reverse the rejection of claims 2, 3, 8 and 10 under 35 U.S.C. § 102(b) as anticipated by Meisner.

Obviousness:

The examiner relies on Meisner as discussed above. The examiner notes, however, that Meisner does not teach that the S-alkylthiol is administered intravenously (see e.g., appellants' claim 7), or is selected from the group consisting of, inter alia, S-methyl-L-cysteine (see e.g., appellants' claim 3).

To make up for these deficiencies, the examiner relies on Joullié to teach that S-methyl cysteine is well known to be injected into an animal for therapeutic purposes, and Chem. Abst. to teach that S-methylcysteine and S-methyl-L-cysteine are indeed the same compound. However, upon careful review of these documents, we find ourselves in agreement with appellants in that neither reference makes up for the deficiency in Meisner, whose composition requires

the presence of a precursor or stimulant of epinephrine or norepinephrine production selected from tyrosine, and phenylalanine.

Accordingly, we reverse the rejection of claims 2-8 and 10 under 35 U.S.C. § 103 as being unpatentable over the combination of Meisner, Joullié and Chem. Abst.

OTHER ISSUES

Upon consideration of the evidence of record, we note that Joullié teaches pharmaceutical compositions comprising S-methylcysteine, which are administered orally and intravenously. See e.g., the LJ 106[3] compositions at column 11, lines 7-45. According to Joullié these compositions "may be administered to human beings in doses from 200 mg to 3 g per day, preferably of 800 mg per day." According to appellants' specification (page 5), the therapeutically effective amount called for in appellants' claimed invention "could range from 100 mg to 10 grams daily. . . ." Thus, the dosage range set forth in Joullié appears to fall within appellants' disclosed therapeutic range.

Accordingly, prior to any further action on the merits, we encourage the examiner to take a step back and reconsider whether Joullié alone, or in

[3] According to Joullié (column 10, line 32), LJ 106 is S-methylcysteine.

combination with any other available prior art, teaches a composition within the scope of appellants' claimed invention.

REVERSED

Donald E. Adams)
Administrative Patent Judge)
)
) BOARD OF PATENT
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Lora M. Green) APPEALS AND
Administrative Patent Judge)
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Richard M. Lebovitz)
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